

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-14 and 28-40 are pending. Non-elected claims 15-27 were withdrawn from consideration by the Examiner. Applicants cancel the non-elected claims without prejudice to future prosecution of that subject matter. The new claims are supported by the original disclosure and, thus, no new matter is added by their entry.

Applicants disagree with the Examiner's allegation on page 3 of the Office Action that claims 2-14 are directed to non-elected subject matter. The only claims directed to non-elected inventions are claims 15-27. Claims 2-14 are directed to the elected invention of Group I. See page 2 of the Office Action mailed November 14, 2007. Withdrawal of the objection is requested.

35 U.S.C. 112 – Written Description

The specification must convey with reasonable clarity to persons skilled in the art that applicant was in possession of the claimed invention as of the filing date sought. See *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). But the Patent Office has the initial burden of presenting evidence or a reason why persons of ordinary skill in the art would not have recognized such a description of the claimed invention in the original disclosure. See *In re Gosteli*, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). A specification need not teach, and preferably omits, what is well known in the art. See *Hybritech v. Monoclonal Antibodies*, 231 USPQ 81, 94 (Fed. Cir. 1986).

Claims 1-3, 5-6 and 8-14 were rejected under Section 112, first paragraph, as they allegedly contain “subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” Applicants traverse because the specification and the art teach a representative number of species within the claimed genus.

Here, in addition to the specific enoate reductase (e.g., Enr) enzymes described on pages 4-7 and N-ethylmaleimide reductase (e.g., NemA) enzymes described on pages 9-10 of the specification, the NCBI database contains at least 940 bacteria, 48

archaea, and 162 eukaryotes with known sequences encoding such enzymes. See below.

Microorganisms known to contain enoate reductase (Enr) enzyme according to a search of the NCBI database by one of the inventors on June 10, 2008.

Microorganism	Number of hits in NCBI database
<i>Clostridium kluyveri</i> DSM 555	19
<i>Bacillus coagulans</i> 3601	4
<i>Aspergillus niger</i>	2
<i>Clostridium acetobutylicum</i> ATCC 824	2
<i>Clostridium tyrobutyricum</i>	2
<i>Clostridium beijerinckii</i> NCIMB 8052	2
<i>Clostridium novyi</i> NT	2
<i>Clostridium botulinum</i> B str. Eklund 17B	2
<i>Natranaerobius thermophilus</i> JW/NM-WN-LF	2
<i>Treponema denticola</i> ATCC 35405	2
<i>Photobacterium profundum</i> 3TCK	2
<i>Vibrio fischeri</i> MJ11	2
<i>Moritella</i> sp. PE36	2
<i>Aspergillus niger</i> CBS 513.88	1
<i>Moorella thermoacetica</i>	1
<i>Clostridium difficile</i> QCD-37x79	1
<i>Clostridium difficile</i> QCD-76w55	1
<i>Clostridium difficile</i> QCD-97b34	1

Microorganisms known to contain N-ethylmaleimide reductase (NemA) enzyme according to a search of the NCBI database by one of the inventors on June 10, 2008.

Microorganism	Number of hits in NCBI database
<i>Escherichia coli</i> K12	9
<i>Streptomyces coelicolor</i> A3(2)	6
<i>Photobacterium profundum</i> SS9	6
<i>Bacillus thuringiensis</i> serovar <i>israelensis</i> ATCC 35646	4
<i>Escherichia coli</i> str. K12 substr. W3110	4
<i>Enterobacter sakazakii</i> ATCC BAA-894	4
<i>Vibrio shilonii</i> AK1	4
<i>Vibrio parahaemolyticus</i> AQ3810	4
<i>Vibrio parahaemolyticus</i> RIMD 2210633	4
<i>Vibrio splendidus</i> 12B01	4
<i>Vibrio</i> sp. MED222	4
<i>Vibrio alginolyticus</i> 12G01	4
<i>Vibrionales bacterium</i> SWAT-3	4
<i>Shewanella oneidensis</i> MR-1	4
<i>Bordetella bronchiseptica</i> RB50	4
<i>Burkholderia phytofirmans</i> PsJN	4
<i>Caulobacter</i> sp. K31	4
<i>Gramella forsetii</i> KT0803	4
<i>Leishmania major</i>	2
<i>Bacillus cereus</i> ATCC 14579	2

Microorganism	Number of hits in NCBI database
All other taxa	247

Note that both enoate reductase and N-ethylmaleimide reductase enzymes are able to catalyze the chemical transformation required by the present claims.

Moreover, claims 2-7 are directed to enzymes originating from particular microorganisms which further restrict the scope of the claims. The use in the examples of Applicants' specification of a few (and, indeed, specifically named) species of such microorganisms is not evidence for the unfounded allegation that related microorganisms do not also contain enzymes that are able to catalyze the chemical transformation recited in the present claims.

Therefore, the multiplicity of enzymes available to the skilled artisan to practice the claimed process shows that Applicants were in possession of the invention. Withdrawal of the written description rejection is requested.

35 U.S.C. 112 – Enablement

The Patent Office has the initial burden to question the enablement provided for the claimed invention. M.P.E.P. § 2164.04, and the cases cited therein. It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. *In re Marzocchi*, 169 USPQ 367, 370 (C.C.P.A. 1971). Specific technical reasons are always required. See M.P.E.P. § 2164.04.

Claims 1-3, 5-6 and 8-14 were rejected under Section 112, first paragraph, as it was alleged that the specification “does not reasonably provide enablement for method of production of 6-amino caproic acid using any enoate reductase with any structure or a broad spectrum of enoate reductase . . .” Applicants traverse.

The above two tables listing the enzymes found by searching the NCBI database establish that enoate reductase and N-ethylmaleimide reductase enzymes were available for use by the skilled artisan. This diverse group of microorganisms demonstrates

the broad scope of enablement for the claims. Knowledge of the sequences of these enzymes shows that undue experimentation would not be required to express enzymes in a suitable host organism. The genera described in the specification and recited in the claims were selected based on the experimental results, the close taxonomic relationship among genera, and the inventors' observations when enriching or growing certain microorganism cultures on relevant substrates.

Further, the skilled artisan is capable of performing standard techniques known in molecular biology and biochemistry as have been described in detail in Rohdich (J. Biol. Chem. 276:5779-5787, 2001) which is cited on page 5, lines 16-17, of the specification. The details provided in the examples (see III.3, III.4 and III.5 of the specification) also demonstrate that the Gateway® cloning technique can be used - by analogy - to clone other α,β -enoate reductase genes into host organisms.

Therefore, the multiplicity of enzymes available to the skilled artisan to practice the claimed process shows that undue experimentation would not be required to make and use the invention. Withdrawal of the enablement rejection is requested.

Conclusion

Finally, it is noted that the citation of Simon et al. at page 9 of the Office Action incorrectly lists its publication date as 1983. It was actually published in 1985.

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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